

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Patent Application of:  
Gregory Gregoriadis, et al.

Application No.: Not Yet Assigned

Group Art Unit: N/A

Filed: Herewith

Examiner: Not Yet Assigned

For: LIPOSOME-ENTRAPPED DNA ORAL  
VACCINES

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**INFORMATION DISCLOSURE STATEMENT (IDS)**Commissioner for Patents  
Washington, DC 20231  
Sir:

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

**Timing of Filing of the Information Disclosure Statement:**

This IDS is being filed before the First Office Action<sup>1</sup>.

This IDS is being filed after the issuance of the First Office Action but before the issuance of a Final Office Action<sup>2</sup>.

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<sup>1</sup> The IDS should, where possible, include a certification under 37 C.F.R. §1.97(e).

<sup>2</sup> The IDS *must* include *either* a certification under 37 C.F.R. §1.97(e) *or* the fee set forth in 37 C.F.R. §1.17(p).

This IDS is being filed after the issuance of a Final Office Action but before the payment of the Final Fee<sup>3</sup>.

**Certifications:**

If checked, the undersigned makes the following statement(s):

Statement under 37 CFR § 1.97(e):

Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement; or

No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

Statement Under 37 C.F.R. § 1.704(d):

Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

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<sup>3</sup> The IDS *must* include *both* a certification under 37 C.F.R. §1.97(e) *and* the fee set forth in 37 C.F.R. §1.17(p).

**Fee Required by 37 C.F.R. § 1.97(c)(2) or 1.97(d)(2):**

If checked, the fee of \$180.00 set forth in 37 C.F.R. §1.17(p) is attached.

**Copies of Information:**

In accordance with 37 C.F.R. §1.98(a), the following are enclosed:

A legible copy<sup>4</sup> of each document (or relevant portion thereof) cited in the attached PTO/SB/08.

With respect to any information which is not in English, a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, is attached. This concise explanation is provided by way of:

A translation of the relevant portions of the non-English language information<sup>5</sup>;

A statement explaining the relevant portions of the non-English language information;

A copy [and, where not in the English language, a translation] of at least the relevant portion(s)<sup>6</sup> of the communication from a foreign patent office in a counterpart foreign application in which the information was cited; or

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<sup>4</sup> A legible copy of the document is not required if (1) the information was previously cited by, or submitted to, the Office and considered by the Office in a prior U.S. application to which this application claims priority, provided that the prior application is properly identified in this IDS, and (2) the IDS submitted in the earlier application complies with 37 C.F.R. § 1.98(a) – (c). This exception does not apply to information cited in an International Application.

<sup>5</sup> 37 C.F.R. §1.98(a)(3)(ii) *requires* that an English language translation be provided when a translation of the document, or portion thereof, “is within the possession, custody or control of, or is readily available to any individual designated in 37 C.F.R. § 1.56(c).”

This information is contained in the specification of the present application.

**Materiality:**

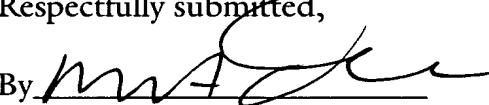
Whether or not the information and references disclosed in this Information Disclosure Statement is "material" pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Dated: March 29, 2002

Respectfully submitted,

By   
Mark J. Thronson

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<sup>6</sup> The relevant portion is that portion which indicates the degree of relevance found by the foreign patent office. This may be an explanation of which portion of the reference is particularly relevant, to which claims it applies, or merely an "X", "Y", or "A" indication on a search report. MPEP §609 III A(3).

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	Not Yet Assigned
Sheet	1	of	1	Filing Date	
				First Named Inventor	Gregory Gregoriadis
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	G0365.0355/P355

<b>U. S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
					<sup>1</sup> <sup>6</sup>
	A	WO 98/10748	03-19-1998		

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See attached Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.			<sup>1</sup> <sup>2</sup>
	B	Gregoriadis et al., "Vaccine Entrapment in Liposomes", Methods 19 pp. 156-162 (1999).			
	C	Perrie et al., "Genetic Immunization Using Liposome-Incorporated DNA", J. Pharm. Pharmacol. 50 (Supplement) 103 (1998)			
	D	Gregoriadis et al., "Liposome-Mediated DNA Vaccination", FEBS Letters 402, pp.107-110 (1997)			
	E	Han et al., "Application of Liposomes for Development of Oral Vaccines: Study of In Vitro Stability of Liposomes and Antibody Response to Antigen Associated with Liposomes After Oral Immunization" Journal of Veterinary Medical Science Vol. 50 No. 12 (December 1997)			

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.